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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
[60Day-15-0010]

Proposed Data Collections Submitted for  
Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of

the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

### **Proposed Project**

Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB 0920-0010, Expiration 01/31/2017) - Revision - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects currently covering three counties in Metropolitan Atlanta.

Since 1997, CDC has funded case-control studies of major birth defects that utilize existing birth defect surveillance registries (including MACDP) to identify cases and study birth defects causes in participating states/municipalities across the United States.

The current study, BD-STEPS, is a case-control study that is similar to the previous CDC-funded birth defects case-control study, NBDPS, which stopped interviewing participants in 2013. As with NBDPS, BD-STEPS control infants are randomly selected from birth certificates or birth hospital records; mothers of case and control infants are interviewed using a computer-assisted telephone interview.

The results from NBDPS have improved understanding of the causes of birth defects. Over 200 articles have been written in professional journals using the data from NBDPS, and BD-STEPS data will soon be

added to NBDPS data for analysis. The current BD-STEPS revision is a change in proposed data collection. Specifically, the study will not ask BD-STEPS participants to participate in saliva collection as originally planned, but we will add an opportunity for some participants to respond to an online questionnaire, and we will also ask some participants for permission to retrieve newborn bloodspots.

The BD-STEPS interview takes approximately forty-five minutes to complete. A maximum of 275 interviews are planned per year per center, 200 cases and 75 controls. With seven centers planned, the maximum interview burden for all centers combined would be approximately 1,444 hours. Mothers in five of the seven BD-STEPS Centers will also be asked to provide consent for the study to access previously collected infant bloodspots. It takes approximately 15 minutes to read, sign and return the informed consent for retrieval of bloodspots. Finally, the newly planned online questionnaire will be offered to approximately one third of participants who report certain occupations during the telephone interview; these participants will be asked to complete additional occupational questions via a website which will take approximately 15 minutes to answer.

Information gathered from both the interviews and the Deoxyribonucleic acid specimens has been and will continue to be used to study independent genetic and environmental factors as well as

gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to revise the previously estimated burden details and to request OMB clearance for three additional years. The total estimated annual burden hours are 1,949.

There are no costs to the respondents other than their time.

**Estimates of Annualized Burden Hours**

Respondents	Activity	Number of Respondents	Number of responses per respondent	Avg. burden per response (In hours)	Total Burden Hours
Mothers (interview)	Telephone consent and BD-STEPS questionnaire	1,925	1	45/60	1,444
Mothers (consent for bloodspot retrieval)	Written consent for bloodspot retrieval	1,375	1	15/60	344
Mothers (online occupational questionnaire)	Online Occupational Questionnaire	642	1	15/60	161
TOTAL					1,949

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